

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:

see form PCT/ISA/220

PCT

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/JP2005/013907

International filing date (day/month/year)
22.07.2005

Priority date (day/month/year)
23.07.2004

International Patent Classification (IPC) or both national classification and IPC
C12Q1/00

Applicant
CANON KABUSHIKI KAISHA

1. This opinion contains indications relating to the following items:

- Box No. I Basis of the opinion
- Box No. II Priority
- Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- Box No. IV Lack of unity of invention
- Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- Box No. VI Certain documents cited
- Box No. VII Certain defects in the international application
- Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITYInternational application No.
PCT/JP2005/013907

IAP20 Rec'd PCT/PTO 23 MAR 2006

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - a sequence listing
 - table(s) related to the sequence listing
 - b. format of material:
 - in written format
 - in computer readable form
 - c. time of filing/furnishing:
 - contained in the international application as filed.
 - filed together with the international application in computer readable form.
 - furnished subsequently to this Authority for the purposes of search.
3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/JP2005/013907

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or
industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | |
|-------------------------------|-------------|------|
| Novelty (N) | Yes: Claims | 1-11 |
| | No: Claims | |
| Inventive step (IS) | Yes: Claims | |
| | No: Claims | 1-11 |
| Industrial applicability (IA) | Yes: Claims | 1-11 |
| | No: Claims | |

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and / or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

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IAP20 Rec'd PCT/PTO 23 MAR 2006

International application No.

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

PCT/JP2005/013907

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

D1: WILLNER I ET AL: "Electrical wiring of glucose oxidase by reconstitution of FAD-modified monolayers assembled onto Au-electrodes" JOURNAL OF THE AMERICAN CHEMICAL SOCIETY, AMERICAN CHEMICAL SOCIETY, WASHINGTON, DC, US, vol. 118, 1996, pages 10321-10322,
D2: US-A-6 033 866 (GUO ET AL) 7 March 2000 (2000-03-07),
D3: US-A-5 525 511 (D'COSTA ET AL) 11 June 1996 (1996-06-11).

2. As the particular combination of features of independent claim 1 is not disclosed in any cited prior art, the subject-matter of the said claim would appear to be novel (Article 33(2) PCT).

3. However, the subject-matter of the said claim does not involve an inventive step in the sense of Art. 33(3) PCT.

Document D1 discloses an enzyme electrode comprising a conductive member and a enzyme wherein a mediator is immobilized onto the conductive member (scheme 1). The subject-matter of claim 1 differs from D1 in that a second mediator, having a redox potential different from the first mediator, is immobilized on the said conductive member.

The technical effect of this difference results in an enzyme electrode with improved electric current density (p.6, l.17-19).

The technical problem to be solved can thus be formulated as being the provision of an improved enzyme electrode.

To solve the said problem the skilled man would turn to D2. The said document relates to a strip sensor constructed in the face-to-face sandwich configuration wherein the first mediator is contained in the electrically conductive layer and the second mediator is contained in a carrier strip sandwiched between the electrode

surfaces (abstract). After having deposited the sample (glucose) to the carrier strip, the electrons are first carried by the second mediator of the carrier strip to the first mediator of the conductive layer which, in turn brings the electrons to the electrode surface (fig. 2). The inventors of the said document were confronted with a similar problem as to in the present application, namely improving the performances of mediated-sensors (col. 1, I.59-67). The solution proposed by the inventors was to provide the sensor with a second mediator (column 2, I.1-9; example 4). Document D2 thus already discloses the advantage in term of performances of a 2-mediator system vs. a 1-mediator system.

Although D2 relates to a strip sensor constructed in the face-to-face sandwich configuration, the skilled man would have been motivated to turn to the said document, confronted to a similar problem as in the present application, and to apply the solution disclosed therein to the sensor of D1, namely binding a second mediator to the conductive support.

By doing so he would not exercise any inventive activity.

NB : Documents D2 and D3 could also be considered as being the closest prior art documents.

As mentioned above, the said document D2 relates to a strip sensor constructed in the face-to-face sandwich configuration wherein the first mediator is contained in the electrically conductive layer and the second mediator is contained in a carrier strip sandwiched between the electrode surfaces (abstract). After having deposited the sample (glucose) to the carrier strip, the electrons are first carried by the second mediator of the carrier strip to the first mediator of the conductive layer which, in turn brings the electrons to the electrode surface (fig. 2).

Document D3 discloses also a sensor comprising a conductive support, an enzyme system including a mediator immobilized on the said support and a covering membrane characterised in that the said membrane incorporates a mediator.

The subject-matter of claim 1 differs from these documents in that the second mediator is also immobilized to the conductive layer.

It would appear that in absence of any technical effect linked to this difference, the subject-matter of claim 1 appears to be a mere constructional change which comes within the scope of the customary practice followed by persons skilled in the art.

The requirements of Art. 33(3) PCT are thus not fulfilled.

Dependent claims 2 to 8 do not appear to contain any additional features which meet the requirements of inventive steps as all the features of these claims fall within the customary practice of the skilled person or are conventional in the art.

Similarly, the sensor of claim 9, the fuel cell of claim 10 and the electrochemical reactor of claim 11 do not fulfil the requirements of Art. 56 EPC.

Re Item VII

Certain defects in the international application

1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D2 and D3 are not mentioned in the description, nor are these documents identified therein.